Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Cellmedix Holdings Centrepid Platelet Concentrator 510(k) premarket notification.

The safety and effectiveness of the Centrepid Platelet Concentrator is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its' predicate devices.

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Proprietary Name: Centrepid™ PC Kit

Common Name: Automated Blood Cell Separator

Regulation Number: 21 CFR 864.9245

Regulatory Class: Class II

Product Code: ORG

Device Description: The **Centrepid™ PC** design concept is predicated on providing an easy to use device for platelet rich plasma (PRP) that demonstrates high platelet yield in a highly reproducible manner. This is accomplished by inclusion of design elements that provide appropriate directional, and selectable, cell layer aspiration within the horizontally dispersed "buffy coat" in the centrifuge tube design. The design resembles the shape, and general construction, of a standard 50 ml centrifuge tube, but differs from such standard products by inclusion of proprietary structural components. The similarities in design allow such devices to be centrifuged in any tabletop centrifuge that accepts a 50 ml tube and is, additionally, capable of 1900 RCF at 3500 RPM, 4X50ml capacity and 30-minute timer. Cellmedix Holdings, LLC recommends using the Eppendorf Centrifuge with Effendorf 5702/Rotor and adaptor Cat.02629883, Aerosol Cap Cat.02263293 and 50ml Adapter Cat.022634450. The standard factory settings of 1900rcf at 3500rpm and run timer specifications meet the **Centrepid™ PC** performance requirements.

Intended Use: Centrepid™ PC Kit is indicated for the rapid preparation of autologous Platelet Rich Plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to the application to a bony defect for improving handling characteristics of the graft.

Predicate Device:

Harvest PRP Separation System, Harvest Technologies, Inc. (BK000037), Harvest PRP Separation System with ACD-A (30ml) (BK100059), Harvest Technologies, Inc., Harvest PRP Separation System with ACD-A (30ml) (BK120038), Harvest Technologies Corp.

Technological and Performance Characteristics: The **Centrepid™ PC** is substantially equivalent to the predicate device in material

composition and is biocompatible for its intended use. Additionally, the materials were determined to be non-hemolytic, did not have an adverse effect on the prothrombin coagulation time of human plasma or on the clotting time of human plasma, and did not adversely affect hematological parameters such as complete blood count including platelets, hematocrit, and erythrocyte indices.

Centrepid™ PC Kit is substantially equivalent to the predicate device with respect to physical characteristics. Each device is designed to accept a volume of whole blood and achieve concentrations of platelet rich and poor plasma from centrifugal processing.

- *The **Centrepid™ PC** and the predicate device both use a centrifuge to spin whole blood into platelet rich and platelet poor plasma.*

The **Centrepid™ PC** manufacturer recommends using the Eppendorf centrifuge Model 5702 with the aerosol carrier #022639293 and adapter #022634450, and predicate device manufacturer (Harvest Technologies) supplies a custom design centrifuge/rotor package to meeting performance specifications.

- *The **Centrepid™ PC Kit** and the predicate device each have a receptacle to hold the whole blood, and ultimately through centrifugal processing, platelet rich and platelet poor plasma.*

Following venipuncture, blood draw, and mixing of the whole blood with ACD-A USP), the whole blood/ACD-A USP solution is dispensed into the **Centrepid™ PC**, and the **Centrepid™ PC** cap is rotated to the "RBC" position. The predicate device also dispenses the ACD-A USP solution into one of the two chambers, the "plasma" (white) chamber, and the whole blood into a second, separate chamber.

Both the **Centrepid™ PC** and the predicate device balance the weight in the centrifuge for optimum centrifugal processing. The **Centrepid™ PC** containing the whole blood/ACD-A USP solution is loaded into a centrifuge. A second **Centrepid™ PC** is filled with 50m of water, and the cap is turned to the "RBC"

position and placed into the centrifuge as a counter balance. The predicate device uses a balance weight loaded into the Harvest SmartPReP centrifuge.

The resultant platelet rich plasma is achieved with both the **Centrepid™ PC** and the predicate device; the red blood cells are drawn from the **Centrepid™ PC**, and the **Centrepid™ PC** is placed into the centrifuge, and the 2nd **Centrepid™ PC** with water, adjusted for the new volume, and the **Centrepid™ PC** is spun a second time.

The predicate device goes through one spin cycle for 14 minutes; the **Centrepid™ PC** goes through two cycles for a total of 13 minutes (5 minutes for the first cycle, 8 minutes for the 2nd cycle).

Following the second spin, the **Centrepid™ PC** cap (containing the PPP) is turned to the "PPP", and the PPP is aspirated using a 30ml syringe; the predicate device also aspirates the PPP using a 10ml syringe.

The remaining PRP is gently mixed, and the **Centrepid™ PC** cap is turned to the RBC position; the predicate device aspirates the PPP as well, by withdrawing the plasma into a syringe, and injected back into the plasma chamber 2-3 times until the platelets are visibly suspended in the plasma.

Centrepid™ PC performance testing confirmed that the **Centrepid™ PC** produces platelet rich plasma at a concentration equal to or greater than the SmartPReP®2
BMAC System/ SmartPReP Platelet Concentration System for the same intended use. Materials were determined to be biocompatible for their intended use.

Substantial Equivalence: The claim of substantial equivalence of **Centrepid™ PC** to the product identified above is based on the comparison of the intended use, product technical characteristics, and performance characteristics.
The different technological characteristics of the **Centrepid™ PC** do not raise different questions of safety and effectiveness than the (primary) predicate device.